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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,488	11/06/2001	Juan A. Vergez	PHUS-58	5176
24039	7590	08/29/2005	EXAMINER	
INNOVAR, LLC P O BOX 250647 PLANO, TX 75025			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/992,488	VERGEZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-122 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,10,11 and 13-122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-9 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/11/02</u> . | 6) <input type="checkbox"/> Other: _____  |

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Applicant's election with traverse of claims 1-3, 5-9, and 12 in the reply filed on 12/17/03 and 6/8/05 is acknowledged. The traversal is on the ground(s) that the method of use requires administration of the claimed pharmaceutical composition. This is not found persuasive because the patentability of the method of use lies in the method steps rather than the composition.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Hsu et al (US 6,562,368).

Hsu et al teach a transdermal comprising oxybutynin (abstract).

Coadministration with other drugs commonly used to treat bladder disorders, including toterodine, is disclosed (column 10 lines 12-20). Manufacturing as a batch is a product-by-process limitation, which is not considered as a patentable limitation during prosecution of composition claims before the USPTO

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal (US 5,399,359) in view of Dmochowski et al and WO 97/18814 (WO '814) or WO 00/12069 (WO '069).

Baichwal et al teach oxybutynin formulations (title). Tableting is disclosed (column 2 line 22). Batch production is specified (column 6 lines 59-60). However, Baichwal et al do not teach oxybutynin with other active agents.

Dmochowski et al teaches that oxybutynin, tolteridine, and darifenacin are all used to treat the overactive bladder (title, p. 43-45, page 46).

WO '814 teaches darifenacin is deliverable in tablets (abstract and page 2 line 23).

WO '069 teaches tolteridine is deliverable in tablets (title, page 6 line 28).

It would have been obvious to one of ordinary skill to add either tolteridine or darifenacin to the composition of Baichwal et al because oxybutynin, tolteridine and darifenacin are all used to treat the overactive bladder in view of Dmochowski et al, the latter two drugs are deliverable in tablets in view of WO '0814 and WO '069, and one of ordinary skill would make the combination to achieve the additive advantages of plural agents demonstrating efficacy for a particular treatment. In re Kerkhoven 205 USPQ 1069 (CCPA 1980). As to the claimed ratios of oxybutynin to second drug, optimum

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such ratios can be obtained by routine experimentation absent a showing of unexpected results or critical ranges. In re Boesch 205 USPQ 215 (1980).

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1600